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VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

Re: Response to CRN Comments to FDA's Notice of Opportunity to Comment on the Status of Pyridoxamine, Docket No. 2005P-0305/CP1

On behalf of BioStratum, Inc. ("BioStratum" or "the Company"), these further comments are being filed to Docket No. 2005P-0305/CP1 (Pyridoxamine Citizen Petition), to respond to the December 16, 2005 comments filed by the Council for Responsible Nutrition ("CRN") in response to the Food and Drug Administration's ("FDA's" or "the Agency's") issuance of a Notice of Opportunity to Comment on the status of pyridoxamine.[1] For the reasons set forth below, BioStratum respectfully requests that FDA disregard CRN's comments in their entirety, and deny CRN's unreasonable and untimely request for an extension of the comment period.

I. CRN Comments

CRN's December 16, 2005 comments are, in essence, a repetition of the CRN comments filed on September 14, 2005 in response BioStratum's July 29, 2005 Citizen Petition (the "Pyridoxamine Citizen Petition"). In both its September and December comments, CRN asserts that: (1) Pyridoxamine is unequivocally a dietary ingredient because it is one of the three primary natural forms of vitamin B6, and it is one of the two predominant forms in animal products used as human foods; and (2) There is very strong evidence that pyridoxamine was marketed as a dietary supplement prior to October 15, 1994, and is therefore an "old" dietary ingredient under the Dietary Supplement Health and Education Act ("DSHEA"). As Biostratum previously

[1] 70 Fed. Reg. 69976 (Nov. 18, 2005).

responded to these comments in its September 29, 2005 submission to this docket, it will not reiterate its objections here, but rather incorporates its September 29 comments by reference.[2]

The only new aspect of CRN's comments is its request that FDA provide a 90-day extension of the comment period on the Notice, to allow CRN additional time to search for evidentiary support of pyridoxamine's grandfathered status. For the reasons set forth below, BioStratum once again requests that FDA dismiss CRN's hollow assertions and deny CRN's request for an extension of the comment period.

A. CRN Has Had Extensive Time to Support its Assertion That Pyridoxamine is Grandfathered

Despite being on notice since July 29, 2005 of BioStratum's position that pyridoxamine cannot be legally marketed as a dietary supplement, CRN's two submissions thus far have only included a conclusory statement that pyridoxamine is a grandfathered ingredient, without any evidentiary support or references. Moreover, CRN's December comments state that CRN only actively sought information from its members about the status of pyridoxamine since November 18, 2005. CRN's near four-month delay in seeking this information after the submission of the Pyridoxamine Citizen Petition does not now justify an extension of the comment period. Even assuming, as CRN contends, that the age of the relevant records may lengthen the amount of time necessary to perform a thorough search, CRN has already had more than an ample opportunity to do so. CRN's deferral in researching its position is neither the fault nor concern of either FDA or BioStratum, and BioStratum should not be forced to bear the consequence of further delay in the Agency's action regarding the Pyridoxamine Citizen Petition.

B. An Extension of the Comment Period Would Serve Only to Delay FDA's Final Decision on the Pyridoxamine Citizen Petition

Given the considerable ingredient research set forth in the Pyridoxamine Citizen Petition, and FDA's tentative conclusion that pyridoxamine is excluded from the dietary supplement definition under the exclusion clause at 21 U.S.C. § 321(ff)(3)(B)(ii), an extension of the comment period likely would not result in any evidence supporting CRN's position. Accordingly, CRN's extension request properly must be viewed as a questionable maneuver to delay FDA's final determination with regard to the Pyridoxamine Citizen Petition. If, as CRN has repeatedly claimed, there does exist "very strong evidence" of the prior marketing of pyridoxamine as a dietary supplement, CRN could certainly have included such evidence along with its comments in either September or December. In lieu of such evidence, CRN has instead referred to two unidentified companies "whose former employees believe they marketed pyridoxamine" prior to October 15, 1994. Such tenuous and uncorroborated facts hardly lead one to anticipate that the promised "very strong evidence" is just around the corner. The questionable nature of the support offered by CRN, coupled with the last-minute timing of its

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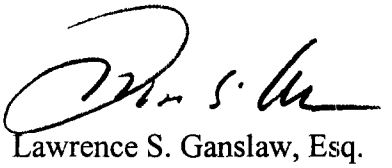
[2] Biostratum Response to CRN Comments to Pyridoxamine Citizen Petition, Docket No. 2005P-0305/CP1 (Sept. 29, 2005).

submission, make plain that CRN is merely seeking to delay the implementation of FDA's logical conclusion that pyridoxamine was not marketed as either a food or dietary supplement prior to October 15, 1994 or prior to BioStratum's Investigational New Drug ("IND") filing in 1999.

As explained in Pyridoxamine Citizen Petition and BioStratum's further comments to this docket, BioStratum has determined that pyridoxamine was not marketed as a food or dietary supplement until after July 1999, when the Company submitted its IND application to FDA to investigate this substance as a drug for the treatment of diabetic nephropathy. CRN has not provided any evidence contrary to BioStratum's conclusions, and quite obviously is unable to do so. Nor has CRN articulated a reasonable justification for its untimely request for additional time to locate this illusory evidence.

Based on the foregoing, FDA should dismiss CRN's unsupported comments, refuse to grant CRN's request for a 90-day extension of the comment period, and provide the relief requested in the Pyridoxamine Citizen Petition.

Sincerely,



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